

(4) Remarks

Claims 1-16 are now present in the application.

No claims have been added or canceled, but they have each been amended to address informalities and to better define the invention.

Specification Objection – MPEP §608.01(b)

The examiner objected to the specification because the abstract is said to be too long. An amended abstract is submitted.

Drawings

The drawings have been objected to as informal and the examiner has indicated that corrections cannot be held in abeyance. Applicant is currently preparing such, but they are not yet ready. Applicant notes that the drawings, while informal, are fully complete and understandable and requests that examination proceed on the basis of the file as it is now.

Applicant notes that MPEP §608.02(a) states, in part:

If the drawings have been indicated by the applicant as informal, but no objection has been made to the drawings by *>OPAP< (drawings considered acceptable by *>OPAP<, the examiner should not require replacement of the “informal” drawings with new drawings.

In the present case there has been no objection by OPAP and no specific objections have been noted. Accordingly, applicant wishes to present the new drawings when they are completed without any delay in the examination process.

Claim Objections – 37 CFR 1.75(c)

The examiner objected to claims 4-16 as being improper in form due to dependencies. The claims have been amended to address this objection, and withdrawal of the objection is believed in order.

Applicant notes that the newly amended claims are directed to the same invention as originally presented and that there is no basis for restriction at this point in the prosecution. This is especially true because the claims in their current form are all patentable over the prior art cited.

Claim Rejections – 35 USC §112, Second Paragraph

Claims 1 through 4 and 12 stand rejected under 35 U.S.C. §112 as being indefinite for various reasons. Again, the claims have been amended to address this rejection, and withdrawal of the rejection is believed in order.

Claim Rejections – 35 USC §102(b)

Claims 1 through 3 stand rejected under 35 U.S.C. §102(b) as being anticipated by both WO 03/090897 and U. S. Patent No. 5,055,263 to Meltzer.

The Office Action asserts that the originally-claimed structure was fully anticipated by the reference; however, citations to the references did not make clear the exact points the examiner was making. To fully address this rejection, applicant has now presented claims which are demonstrably different from the references applied.

WO 03/0908097 A1 discloses a method and a device for handling fluid samples (p. 1, l. 6 - 25), which is clearly insufficient to anticipate the claims as now presented. The reference shows a first container placed in a first process path and a sample of interest is transferred into the first container (p. 1, l. 31 - 24). After mixing the sample in the first container with a reagent (p. 1, l. 34 – p. 2, l. 1), an item of interest in the first sample is separated from the residual contents of the first sample and transferred into a second container in a second process path (p. 2, l. 1 - 10). The items of interest are bound to magnetically responsive particles and can be moved between different positions within the container by use of permanent magnets (p. 11, l. 24 – 31 and p. 12, l. 7 - 12). Thereby, permanent magnets are acting on the magnetically responsive particles from outside, through the sidewalls of the container (p. 56, l. 15 – 19; Fig. 47). Especially, the movement of the magnetically responsive particles between different

positions within the container has the effect that evacuation or aspiration of residual fluid from the container is more effective and/or reduces the extent of magnetic particle loss (p. 56, l. 19 - 25).

In contrast to the invention, WO 03/0908097 A1 does not disclose a carrier element with several carrier plates that can be lifted and lowered individually in the z-direction and whereby at least one of the carrier plates carries a plurality of magnetic or magnetisable transfer elements that can be lowered in z-direction into sample containers or reagent containers for magnetically attaching magnetic microparticles located in said containers.

Accordingly, the rejection over WO 03/0908097 A1 should be withdrawn.

The other cited reference, US 5,055,263 to Meltzer, relates to an automated pipetting system with multiple pipetting probes with individual positioning and metering controls (col. 1, l. 5 - 8).

In contrast to the invention, Meltzer describes neither magnetic microparticles nor magnetic or magnetisable transfer elements.

Claim 1 has been amended to more precisely define important aspects of the invention in order to overcome the clarity objections raised in the Office Action and to address points of novelty over the cited art.

In particular, claim 1 states that the transfer elements can be lowered in z-direction into sample containers or reagent containers for magnetically attaching magnetic microparticles located in said containers and after lifting the transfer elements in z-direction, transporting the magnetic microparticles attached to the transfer elements in x-direction by movement of the carrier element, and after lowering the transfer elements in z-direction into further reagent containers releasing the magnetic microparticles attached to the transfer elements into the further reagent containers.

Additionally, claims 9 and 10 (containers and membranes) have been rewritten as dependent from claim 1 or claim 9, respectively. Method claim 11 has also been clarified by amendment.

As apparent from the above analysis, none of the cited documents discloses a device with all the features of claim 1. Moreover, neither of the references discloses a method with all the features of claim 11.

Therefore, independent claims 1 and 11 are novel.

While there is not currently a rejection based on obviousness, applicant notes that the references could not be combined in any rational fashion without changing the mode of operation of both references. And, even then, the structure would fail to teach or suggest the structure and method now claimed.

If WO 03/0908097 A1 were said to represent the closest prior art because it relates to the handling of magnetic particles in fluids, it must fail as a teaching reference for establishing obviousness because it is silent on the features of the invention now claimed more particularly or the reasons why they are functionally as effective as they are.

In contrast to WO 03/0908097 A1, the invention as defined in claim 1 features special transfer elements (*e.g.*, permanent magnets with membranes or electromagnets) that can be lowered into sample and reagent containers. Furthermore, according to the invention, sample containers with magnetic microparticles can be introduced into a central process area in x-direction while reagent containers can be supplied to the same central process area in a different direction (y-direction) and ejected in the same direction.

Advantageously, the inventive transfer elements make it possible to automatically separate the solid and liquid phase of a suspension and purify magnetic microparticles loaded with organic substances without the need of pipetting probes. Specifically, the inventive transfer elements facilitate to fully remove the magnetic particles from the sample containers and thereby separating them from the liquid phase. Subsequently, the magnetic particles can

easily be released in reagent containers for further treatment. The introduction of sample and reagent containers to a central process area from different directions significantly improves the overall process speed. Especially, time consuming complex movements of sample and reagent containers can be reduced at best. Due to the fact that the processing of the samples takes place in one central process area of limited space, the driving system of the inventive transfer elements (carrier plates) can be built as compact as possible.

Concerning magnetic transfer systems, WO 03/0908097 A1 only describes moveable magnets that can be used to move magnetic particles between different positions in a container. According to a first aspect, retractable magnets can be moved in horizontal direction proximate to the side wall of the container in order to attract magnetic particles at a predefined position at the inside wall of the container (p. 11, l. 24 - 31). In another aspect, containers can be moved with respect to fixed magnets (p. 57, l. 14 - 24). However, magnets are unexceptionally acting on the magnetically responsive particles from outside through the side walls of the container (p. 56, l. 15 - 19; Fig. 47). Accordingly, the magnets according to WO 03/0908097 A1 cannot enter into a sample container in order to pick up and remove a magnetic particle from said container. Consequently, for transferring magnetic particles between different containers, the system according to WO 03/0908097 A1 requires additional and expensive pipetting systems. The inventive solution allows avoiding such pipetting systems completely. Furthermore, WO 03/0908097 A1 does not suggest at all to replace the pipetting systems by magnetic or magnetisable transfer elements.

Furthermore, WO 03/0908097 A1 does neither suggest to perform all steps of the sample processing in one central process area nor to introduce sample and reagent containers from different specific directions. According to the teaching of WO 03/0908097 A1, the processing of the samples takes place at separated positions (different process paths).

According to the reference teachings, it is only required that the containers are reachable by the automatic pipetting system. Whether containers are located on a fixed position or in a carousel is of minor importance. Since the automatic pipetting system is able to freely move to any desired location, there is no need for special positioning facilities for the

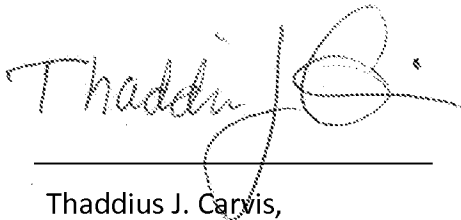
containers. Consequently, WO 03/0908097 A1 does not motivate the person skilled in the art to implement the inventive arrangement whereby sample containers can be introduced into a central process area in x-direction while reagent containers can be supplied to the central process area in a different direction (y-direction) and ejected in the same direction. Importantly, only these inventive features allow the construction of a device capable of automatic separation of the solid and liquid phase of a suspension and for purifying magnetic microparticles and to make the device as compact as possible.

Meltzer discloses only an automatic pipetting system with a plurality of individually controllable pipettes. Significantly, Meltzer is completely silent about the handling of magnetic particles and special arrangements for introducing sample or reagent containers into a process area. Consequently, Meltzer does not motivate the person skilled in the art to implement the inventive arrangement whereby sample containers can be introduced into a central process area in x-direction while reagent containers can be supplied to said central process area in a different direction (y-direction) and ejected in the same direction.

Therefore, even a combination of WO 03/0908097 A1 with Meltzer would not render obvious the inventive solution.

Applicant has endeavored to place the application in condition for allowance, but if for any reason the examiner sees need for formal changes, he is invited to call the undersigned. Accordingly, reconsideration and allowance of all claims are believed in order and are earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Thaddius J. Carvis". The signature is written in dark ink and is positioned above a horizontal line.

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